

NOVARTIS AG  
Form 6-K  
July 19, 2011

# **SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

## **FORM 6-K**

**REPORT OF FOREIGN PRIVATE ISSUER  
PURSUANT TO RULE 13a-16 or 15d-16 OF  
THE SECURITIES EXCHANGE ACT OF 1934**

**Report on Form 6-K dated July 19, 2011**

**(Commission File No. 1-15024)**

---

**Novartis AG**

(Name of Registrant)

**Lichtstrasse 35**

**4056 Basel**

**Switzerland**

(Address of Principal Executive Offices)

---

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F:

Edgar Filing: NOVARTIS AG - Form 6-K

**Form 20-F: x**    Form 40-F: o

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Yes: o    **No: x**

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

Yes: o    **No: x**

Indicate by check mark whether the registrant by furnishing the information contained in this form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes: o    **No: x**

---

**Novartis International AG**  
Novartis Global Communications  
CH-4002 Basel  
Switzerland  
<http://www.novartis.com>

**- Investor Relations Release -**

**Novartis delivers strong financial results and four major approvals in second quarter of 2011**

- **Novartis achieved 19% sales growth in constant currencies and excellent operating leverage in the second quarter**
- **Net sales grew 27%** (+19% in constant currencies, or cc) to USD 14.9 billion; first half up 21% (+16% cc) to USD 28.9 billion
- **Core operating income rose 29%** (+30% cc) to USD 4.2 billion; **core margin up 0.4 percentage points** (+2.6 percentage points cc)
- **Core EPS increased 23%** (+25% cc) to USD 1.48
- **Free cash flow grew 39%** to USD 3.3 billion
- Shareholder returns and a sound capital structure remain a priority; limit on dividend payments to 35-60% of net income lifted
- **Healthcare portfolio and portfolio rejuvenation strengthen foundation for future growth**
- Diversified healthcare portfolio generated sales and profit growth ahead of market with strong contributions from Alcon, Sandoz and Consumer Health
- Recently launched products grew 46% over previous-year quarter to USD 3.8 billion

## Edgar Filing: NOVARTIS AG - Form 6-K

- Best-in-class *Gilenya* launch with USD 138 million in first half sales
- Commitment to innovation results in four major approvals and two major filings
- FDA approved *Afinitor* for advanced pancreatic neuroendocrine tumors and *Arcapta Neohaler* for chronic obstructive pulmonary disease
- EU granted approval for *Lucentis* in retinal vein occlusion and for hypertension medicine *Rasilamlo*
- Janus kinase inhibitor **INC424** was filed for myelofibrosis in Europe; FDA accepted application to expand *Menveo* indication to toddlers and infants as young as 2 months

### Key figures

	Q2 2011 USD m	Q2 2010 USD m	% change			H1 2011 USD m	H1 2010 USD m	% change		
			USD	cc				USD	cc	
Net sales	14 915	11 716	27	19		28 942	23 847	21	16	
Operating income	3 322	2 961	12	15		6 730	6 472	4	7	
Net income	2 726	2 437	12	17		5 547	5 385	3	7	
EPS (USD)	1.13	1.06	7	12		2.33	2.34	0	3	
Free cash flow	3 297	2 368	39			4 919	5 271	-7		
<b>Core(1)</b>										
Operating income	4 235	3 276	29	30		8 247	7 141	15	17	
Net income	3 564	2 771	29	31		6 940	6 080	14	16	
EPS (USD)	1.48	1.20	23	25		2.88	2.65	9	11	

**Basel, July 19, 2011** Commenting on the results, Joseph Jimenez, CEO of Novartis, said:

*Excellent execution behind a sound strategy resulted in another successful quarter for Novartis. We achieved strong sales growth of 19% in constant currencies and margin improvement of 0.4 percentage points in US dollars. We further demonstrated the success of our R&D strategy with four major approvals and two filings in the second quarter. Our diversified healthcare portfolio, focused on high growth segments, is enabling us to generate superior results.*

## **GROUP REVIEW**

### **Second quarter**

Net sales rose 27% (+19% cc) to USD 14.9 billion. Currency benefited sales by 8% as the US dollar weakened against most currencies. Recently launched products grew 46% over the previous-year quarter, contributing USD 3.8 billion to total net sales for the Group.

Pharmaceuticals net sales grew 10% (+2% cc) to USD 8.3 billion, driven by 8 percentage points of volume growth, partly offset by a negative pricing impact of 1 percentage points and the negative impact of generic entries and product divestments of 5 percentage points. Recently launched products contributed USD 2.3 billion or 28% of Pharmaceuticals sales, an increase of 34% in constant currencies over the second quarter of 2010. Alcon contributed USD 2.6 billion of net sales in the second quarter. On a pro forma basis, Alcon grew 12% (+6% cc), with robust growth across geographies and products. Sandoz had an excellent quarter with net sales up 25% (+16% cc) to USD 2.5 billion, driven by 26 percentage points of volume growth, partly offset by a negative pricing impact of 13 percentage points. Vaccines & Diagnostics declined 47% (-50% cc) due to A(H1N1) pandemic flu vaccine sales of approximately USD 200 million in the second quarter of 2010; excluding this, sales declined due to timing of product shipments to key customers. The two Consumer Health businesses, OTC and Animal Health, together grew 5% in constant currencies. OTC's strong growth ahead of market was driven by US, Canada and Germany as well as double-digit net sales growth in key emerging markets. Animal Health achieved strong performance in Europe and emerging markets, which offset increasing competition in the US Companion Animal Business compared to last year.

Operating income was up 12% (+15% cc). Currency had a negative impact of 3%, as the benefit of a weaker dollar against most currencies was offset by an exceptionally strong Swiss franc. Exceptional items in operating income in the second quarter of 2011 include a divestment gain of USD 324 million on the sale of Elidel®, offset by impairment charges in Vaccines & Diagnostics (USD 62 million) and Pharmaceuticals (USD 107 million), provisions for legal cases in Sandoz (USD 150 million), restructuring and impairment charges relating to the streamlining of our manufacturing network (USD 44 million) and Alcon integration costs (USD 80 million).

Core operating income, which excludes exceptional items and amortization of intangible assets, increased 29% (+30% cc). We generated excellent operating leverage in the quarter with core operating income margin increasing by 2.6 percentage points in constant currencies.

Currency reduced the core operating margin by 2.2 percentage points, resulting in a net increase of 0.4 percentage points to 28.4 %.

Pharmaceuticals grew core operating income by 6% in constant currencies on good cost management; Alcon contributed USD 947 million to core operating income, growing 12% (+8% cc) on a pro forma basis; Sandoz was up by 49% in constant currencies; and Consumer Health was up by 9% in constant currencies. Vaccines & Diagnostics reported a loss from the absence of A(H1N1) pandemic flu vaccine revenues and continued investment in the meningococcal disease and early vaccines portfolio.

## Edgar Filing: NOVARTIS AG - Form 6-K

Net income increased 12% (+17% cc) on strong operating income growth, benefiting from an improved tax rate of 16.0% (17.6% in the previous-year period), partially offset by lower income from associated companies. Core net income grew 29% (+31% cc). EPS advanced 7% (+12% cc) and core EPS was up by 23% (+25% cc) at a lower rate than net income as a result of the Alcon related share increase.

Free cash flow of USD 3.3 billion was 39% higher than in the previous year, primarily due to higher operating income, cash inflow for the Elidel® divestment (USD 420 million) and improved working capital.

---

**First half**

Net sales rose 21% (+16% cc) to USD 28.9 billion. Currency had a positive impact of 5 percentage points as the US dollar weakened against most currencies. Recently launched products grew 47% over the first half of 2010, contributing USD 7.1 billion to total net sales for the Group.

Pharmaceuticals net sales grew 8% (+3% cc) to USD 16.0 billion, driven by 8 percentage points of volume growth, partly offset by a negative pricing impact of 1 percentage points and the negative impact of generic entries and product divestments of 4 percentage points. Recently launched products contributed 27% of Pharmaceuticals sales (USD 4.3 billion), compared to 21% in the same period in 2010. Alcon contributed USD 5.0 billion of net sales in the first half, growing 11% (+7% cc) on a pro forma basis, underpinned by strong growth in surgical and ophthalmic pharmaceuticals. Sandoz sales grew 22% (+17% cc) compared to the first half of 2010, driven by 25 percentage points of volume growth, led by strong performances in the US, Canada, Western Europe and emerging markets, which more than compensated for 11 percentage points of price erosion. Vaccines & Diagnostics declined 65% (-66% cc) due to 2010 A(H1N1) pandemic flu vaccine sales of USD 1.3 billion; excluding this, sales grew 6% in constant currencies driven by our meningococcal disease and influenza franchises. The two Consumer Health businesses delivered good sales growth of 13% (+8% cc) in the first half of 2011, with both OTC and Animal Health outpacing their respective markets.

Operating income advanced 4% (+7% cc), with currency movements depressing the result by 3 percentage points. Exceptional items in operating income in the first half of 2011 include divestment gains in Pharmaceuticals on the sale of ophthalmic pharmaceuticals required for approval of the Alcon merger (USD 81 million), a gain of USD 183 million resulting from a legal settlement in the Alcon Division and USD 324 million in divestment income from the sale of Elidel®. These positive items were offset by charges and provisions for legal cases (Sandoz USD 178 million), restructuring and impairment charges relating to the streamlining of our manufacturing network (USD 99 million), the impairment of financial assets in Vaccines & Diagnostics (USD 81 million), intangible asset impairment charges in Pharmaceuticals (USD 107 million) and Alcon integration costs net of a divestment gain of a lens care product (USD 71 million).

Core operating income, which excludes exceptional items and amortization of intangible assets, increased 15% (+17% cc). We generated good operating leverage in the first half with core operating income margin increasing by 0.3 percentage points in constant currencies. Currency reduced the core operating margin by 1.7 percentage points, resulting in a net decrease of 1.4 percentage points to 28.5 %. Pharmaceuticals achieved core operating income growth of 7% (+8% cc) due to good cost management. Alcon contributed USD 1.8 billion to core operating income, growing 10% (+8% cc) on a pro forma basis. Vaccines & Diagnostics reported an operating loss mainly due to the absence of A(H1N1) pandemic flu vaccine revenues (USD 1.3 billion in 2010). Sandoz was up by 31% (+33% cc) and Consumer Health was up by 17% (+26% cc).

Net income grew 3% (+7% cc) on strong operating income growth, benefiting from an improved tax rate of 16.0% (from 17.0%), partially offset by lower income from associated companies. Core net income increased 14% (+16% cc). EPS was USD 2.33, broadly in line with the previous year as a result of the increased share count following the Alcon merger. Core EPS was USD 2.88, an increase of 9% (+11% cc).

Free cash flow of USD 4.9 billion was 7% lower than the previous year, primarily due to higher seasonal working capital.

**Executing on innovation, growth and productivity**

The Novartis growth strategy is based on providing a comprehensive set of healthcare solutions. We are the only healthcare company with leading positions in pharmaceuticals, eye care, generics, vaccines and diagnostics, over-the-counter medicines and animal health.

## Edgar Filing: NOVARTIS AG - Form 6-K

We expect our broad portfolio to allow us to maintain our growth momentum into the future and adapt ahead of changes to the healthcare marketplace. At the core of this strategy is our continued commitment to innovation, growth and productivity: innovation to expand and rejuvenate our portfolio and allow us to bring new healthcare solutions to patients in need; growth to enter new markets and meet the changing demands of patients around the world; and productivity to operate as efficiently as possible, freeing up resources for future investment in R&D.

---



**Accelerating growth to provide healthcare solutions worldwide**

In the second quarter, our diversified healthcare portfolio once again generated growth ahead of the market, with Alcon, Sandoz and Consumer Health delivering particularly strong performances. Benefiting from our continued investment in innovation to expand and rejuvenate our portfolio, recently launched products achieved strong volume growth in the second quarter, allowing us to absorb the effects of pricing, generic competition and divestments. Overall we achieved an underlying volume growth of 7%.

In line with our overall growth strategy, emerging markets are increasingly contributing to our business expansion. Net sales in our top six emerging markets rose 27% (+19% cc) to USD 1.5 billion in the second quarter of 2011. These six markets – Brazil, China, India, Russia, South Korea and Turkey – represented 10% of total net sales in the quarter. Reflecting our commitment to accelerating growth in dynamic new markets worldwide, we started construction on a new state-of-the-art manufacturing facility in St. Petersburg, Russia. This investment is part of a greater commitment in local infrastructure and collaborative healthcare initiatives planned in Russia over a five-year period.

Pharmaceuticals volume grew 8% in the second quarter, with significant contributions from recently launched products more than offsetting generic competition. In particular, *Gilenya*, launched in the US in October 2010 and in parts of the EU following approval in March 2011, is continuing its strong growth trajectory and outpacing all previous launches in multiple sclerosis with sales of USD 79 million in the second quarter. *Tasigna* (USD 170 million, +79% cc) also provided strong growth as a next-generation targeted therapy for chronic myeloid leukemia (CML), as studies continue to show its superiority even to *Glivec* in treating patients with this life-threatening blood cancer. *Tasigna* now represents 17% of our total CML franchise in the US, where it was launched in the third quarter of 2010. Additionally, *Lucentis* (USD 541 million, +27% cc) made an important contribution to Pharmaceuticals growth, as it continues to be the only approved medicine to significantly improve vision in patients with wet age-related macular degeneration (AMD). Furthermore, in the first half of 2011, two new indications were granted for *Lucentis* in the EU in diabetic macular edema and retinal vein occlusion.

The new Alcon Division, which now also includes the CIBA Vision contact lens and lens care business and select Novartis ophthalmic medicines, delivered robust growth in the second quarter. With the new organizational structure implemented in the second quarter, Alcon is now a fully integrated division of Novartis. Pro forma net sales rose 12% (+6% cc) to USD 2.6 billion with balanced contributions across geographies and products, fueled by the successful execution of new product launches. Sales in markets outside the US contributed strongly to overall growth with sales up 18% (+7% cc), driven by the ophthalmic pharmaceutical and surgical product categories. Sales in the top six emerging markets increased 29% (+21% cc), led by Russia, India and China. Alcon also achieved an important milestone in the second quarter for *Patanol*, the world's leading prescription eye drop for allergic conjunctivitis, prevailing in a US patent infringement lawsuit in the Southern District of Indiana. The US District Court's decision will help Alcon defend its intellectual property rights ahead of *Patanol*'s patent expiration in 2015.

Sandoz continued its strong performance in the second quarter, achieving double-digit growth of 25% (+16% cc), driven by strong results in the US, where growth was up 48% in constant currencies, Western Europe (+19% cc) and Latin America (+18% cc). Another key driver of growth for Sandoz was our continued strength in biosimilars, with second-quarter sales up 31% in constant currencies over the previous year. Recently launched products, such as enoxaparin, gemcitabine and lansoprazole oral disintegrating tablets, also made significant contributions to overall growth.

Vaccines & Diagnostics declined 47% (-50% cc) in the second quarter due to 2010 A(H1N1) pandemic flu vaccine sales (approximately USD 200 million). Excluding this, sales declined due to delays of product shipments from one production facility, partially offset by second-quarter growth in the meningococcal disease and influenza franchises.

The Consumer Health businesses also performed well, growing 13% (+5% cc) in the second quarter versus previous year. The continued focus of OTC on priority brands delivered strong results, with several of those brands growing at a double-digit rate over the prior-year period, offsetting a sales decline from expired distribution contracts and divested brands. Animal Health grew ahead of the market outside the US in the second quarter, with strong sales of the cat and dog dewormer *Milbemax* in Europe and of the anti-infective *Denagard* in the US, China and Brazil. Strong growth in the top six emerging markets in both businesses contributed significantly to overall performance.

---

## **Investing in innovation**

The foundation of our success is our ability to develop new innovative treatments. Our industry-leading commitment to R&D enables us to continually expand our pipeline, leading to sustained growth. More importantly, we expect our R&D investments to allow us to achieve breakthroughs in crucial areas of unmet patient need. In the second quarter of 2011, we made important strides in innovation, with four major approvals, two major filings and significant results for new products and indications.

### **Four major approvals**

In Europe, *Rasilamlo*, our single-pill combination therapy for patients with uncontrolled high blood pressure, was granted approval. We also received EU approval for a new indication of *Lucentis* to treat visual impairment due to macular edema in patients suffering from retinal vein occlusion (RVO), a sudden-onset disease associated with debilitating vision loss.

In the US, the FDA granted approval for *Arcapta Neohaler* (indacaterol), a novel once-daily bronchodilator for chronic obstructive pulmonary disease (COPD). The FDA also approved *Afinitor* (everolimus) as the first new treatment in nearly three decades for patients with advanced neuroendocrine tumors of pancreatic origin, a highly aggressive cancer for which treatment options have been limited.

Additionally, indacaterol was approved in Japan under the brand name *Onbrez* Inhalation Capsules. Everolimus was approved in Switzerland under the name *Votubia* as a treatment for subependymal giant cell astrocytoma (SEGA), a benign brain tumor associated with tuberous sclerosis, and received a positive opinion from the EMA's Committee for Medicinal Products for Human Use (CHMP) for approval in Europe.

### **Two major filings**

We filed an application in the EU for our in-licensed Janus kinase inhibitor INC424 to treat patients with myelofibrosis, a life-threatening blood cancer characterized by bone marrow failure and debilitating symptoms. In addition, the FDA accepted our application to expand the indication of our meningococcal vaccine *Menveo* to include infants and toddlers as young as 2 months, based on data from more than 6,000 children in this age group worldwide.

### **Significant pipeline news**

At the American Society of Clinical Oncology (ASCO) annual meeting, Oncology showcased 140 abstracts. Highlights include a Phase III study demonstrating that extending the post-surgical duration of *Glivec* treatment from one to three years can significantly improve survival in patients with gastrointestinal stromal tumors. In addition, we presented data from two Phase III studies of the Janus kinase inhibitor INC424 that show promise for patients with myelofibrosis, a life-threatening blood cancer characterized by bone marrow failure and debilitating symptoms. We also presented a study of patients with chronic myeloid leukemia that shows patients on *Tasigna* are less likely to develop mutations than those taking *Glivec*.

Also in the second quarter, two Phase III studies in patients with severe gouty arthritis showed that ACZ885, currently marketed as *Ilaris* for the rare disease cryopyrin-associated periodic syndrome (CAPS), provides superior pain relief and reduces the risk of new attacks by up to 68% compared to the anti-inflammatory standard of care. On June 21, 2011, an FDA advisory panel voted in favor of the overall efficacy but not the overall safety of ACZ885 to treat gouty arthritis attacks in patients not obtaining adequate relief with non-steroidal anti-inflammatory drugs or

## Edgar Filing: NOVARTIS AG - Form 6-K

colchicine. The committee members raised the potential for use in a narrower population of gouty arthritis patients, and Novartis is currently working with the FDA to identify the right patients who might benefit from this therapy.

In addition, two Phase III studies added to the growing body of evidence that indacaterol, approved in the EU under the brand name *Onbrez Breezhaler*, is an effective treatment for patients with chronic obstructive pulmonary disease (COPD). The studies showed that when used in conjunction with tiotropium, indacaterol produces a significantly greater improvement in lung function than tiotropium alone. Separately, a Phase III study showed that once-daily NVA237 is superior to placebo and similar to tiotropium in improving lung function in patients with moderate-to-severe COPD. This data will be used to support our first regulatory submission for NVA237, which we plan to file by the end of 2011.

---

In July, an interim analysis of a pivotal Phase III study showed that *Afinitor* in combination with exemestane significantly extended progression-free survival, or time without tumor growth, when compared to placebo plus exemestane in postmenopausal women with metastatic breast cancer whose disease has progressed, despite initial endocrine therapy. We are planning to make worldwide regulatory submissions in the second half of 2011. Additionally, a Phase III trial of *Afinitor* in patients with tuberous sclerosis met the primary endpoint of reducing subependymal giant cell astrocytomas (SEGAs) tumor size.

In Vaccines and Diagnostics, two pivotal studies of vaccine candidate *Bexsero* showed promise for protecting infants against meningococcal serogroup B, a deadly strain of meningococcal disease most dangerous for infants and young children.

### **Enhancing productivity to reinvest for future growth**

In order to free up resources and ensure continued investment in R&D, we are focused on improving efficiency and reducing costs across the entire business. We delivered good operating leverage in the second quarter with sales growing 19% (cc), core operating income up 30% (cc) and core operating income margin improving by 2.6 percentage points (cc). On an underlying basis – excluding the impact of A(H1N1) pandemic flu vaccine from 2010 and the merger with Alcon – core operating income margin improved by 2.3 percentage points (cc). This demonstrates the progress the Group continues to make to drive productivity and improve operating performance. In the first half, underlying core operating income margin improved by 2.2 percentage points (cc).

Part of maximizing productivity is actively managing and prioritizing our portfolio. In the second quarter, we sold the global rights to manufacture, market and commercialize Elidel® to Meda for a total cash payment of USD 420 million. This agreement, as well as the discontinuation of the development program PTK796, reflects our strategy of prioritizing investments and focusing our commercialization efforts on new product launches and core brands.

We also made further progress in our efforts to optimize our manufacturing footprint. We concluded the divestment of a Sandoz site in Jena, Germany, and announced our exit from a CIBA Vision production site in Cidra, Puerto Rico. We recorded charges related to exits and inventory write-offs of USD 44 million in the second quarter of 2011, and USD 162 million cumulatively since the program began in the fourth quarter of 2010. With these steps we are reducing excess capacity and enabling the shift of strategic production to technology competence centers.

### **Cash flow**

The sustainability of our strategy lies with the generation of cash flow that provides the resources for reinvestment and creates shareholder return. Cash flow is driven by a continued focus on the cash conversion cycle and operational cash flow improvements. Free cash flow was USD 3.3 billion for the second quarter, an increase of 39% over the previous year. For the first half free cash flow was USD 4.9 billion, 7% lower than the previous year.

### **Capital structure and net debt**

Strong cash flows and a sound capital structure have allowed Novartis to invest in the future of its business through R&D investments and acquisitions even in turbulent times while keeping a double-A rating as a reflection of financial strength. Retaining a good balance between attractive shareholder returns, investment in the business and a sound capital structure will remain a priority in the future. To this end, the Board of Directors has decided to remove the restriction that limits the payment of dividends to 35-60% of net income.

During the quarter, Novartis completed the share repurchase program committed to at the time of the Alcon merger announcement. This program aggregated USD 5.0 billion, of which USD 1.8 billion (30 million shares) was undertaken in the second quarter.

As of June 30, 2011, net debt stood at USD 21.9 billion, with USD 6.0 billion outstanding on the commercial paper programs. This represents a net increase of USD 7.0 billion since December 31, 2010, mainly as a result of the cash used for the dividend payment (USD 5.4 billion) as well as Alcon related share repurchases and contingent value amount (USD 5.3 billion). The long-term credit rating for the company continues to be double-A (Moody's Aa2; Standard & Poor's AA-; Fitch AA).

---

**2011 Group outlook**

**(Barring unforeseen events)**

During the second quarter, the Group revised its divisional structure following the successful completion of the Alcon merger on April 8, 2011 and the majority acquisition in August 2010. All data in this release is based on the new divisional structure, published on May 18, 2011, including the outlook.

Group constant currency sales growth is expected to be around the double-digit mark, based on consolidation of Alcon for four months in 2010.

Pharmaceuticals is expected to deliver sales growth in low- to mid-single digits, with volume growth more than offsetting the impact of generic competition. Alcon sales are expected to increase at a mid- to high-single digit rate on a pro forma basis. Sandoz is expected to deliver mid- to high-single digit sales growth.

With the continuing drive to generate productivity improvements across the Group, we expect to improve constant currency core operating income margin while absorbing price cuts, generic competition and the loss of sales from the A(H1N1) pandemic flu vaccine, and while investing for the future.

During the second quarter, the dollar weakened against most currencies. As a result, if June average exchange rates prevail for the remainder of the year, we expect that the impact would be positive (+5%) on sales and negative (-3%) on operating income for the full year.

---

**HEALTHCARE BUSINESS REVIEW**

**Pharmaceuticals**

	Q2 2011 USD m	Q2 2010 USD m	% change			H1 2011 USD m	H1 2010 USD m	% change		
			USD	cc				USD	cc	
Net sales	8 338	7 609	10	2		16 036	14 836	8	3	